UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES,
AND TOXIC SUBSTANCES

June 8, 2009

MEMORANDUM:

Subject: Occupational and Residential Exposure and Risk Assessments for the New Uses of 1,2-Benzisothiazol-3(2H)-one, 2-butyl (B-BIT)

To: Marshall Swindell, Product Manager
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DP Barcodes: 358428 and 358434

Chemical No.: 098951

Chemical Name: 1,2-Benzisothiazol-3(2H)-one, 2-butyl (B-BIT)

1.0. Action Requested

The Antimicrobial Division's (AD) Regulatory Management Branch I has requested that Risk Assessment and Science Support Branch (RASSB) conduct exposure and risk assessments to support Arch Chemical Inc.'s (Arch) application for an amendment to the Vanquish 100 Antimicrobial (EPA Reg. No. 1258-1249) and Densil DG45 Fungicide (EPA Reg. No. 1258-1286) labels to include two new materials preservation uses which are construction materials and wood coatings and stains. 1,2-Benzisothiazol-3(2H)-one, 2-butyl (B-BIT) is the active ingredient in these two products.

2.0. Summary of Findings

Based on the use patterns for the proposed new use of B-BIT, RASSB concludes that the Margins of Exposure (MOEs) for the following ***dermal*** screening-level scenarios exceed the Agency's level of concern (i.e., less than the target MOE of 100):

- ST/IT dermal **occupational** exposure for Vanquish100 and Densil DG45 wood stain, paint, and coating applications using an airless sprayer: MOE = 37
- ST/IT dermal **occupational** exposure for Vanquish100 and Densil DG45 wood stain, paint, and coating applications using a brush/roller: MOE = 78
- ST/IT dermal **residential** exposure for Vanquish100 and Densil DG45 wood stain, paint, and coating applications using an airless sprayer: MOE = 59
- ST/IT dermal **occupational** exposure for Densil DG45 coatings including wood coatings and stain applications using an airless sprayer: MOE = 41
- ST/IT dermal **occupational** exposure for Densil DG45 coatings including wood coatings and stain applications using a brush/roller: MOE = 86
- ST/IT dermal **residential** exposure for Densil DG45 coatings including wood coatings and stain applications using an airless sprayer: MOE = 66

The MOEs for the remaining new uses on the Vanquish100 and Densil DG45 labels do not exceed Agency's level of concern (i.e., MOEs are greater than the target MOE of 100). Furthermore, all of the inhalation MOEs are greater than 1,000 therefore an inhalation specific toxicity study is not warranted to support these new uses.

3.0. Background

AD's Regulatory Management Branch I, received an application from Arch Chemicals for an amendment to the Vanquish 100 Antimicrobial label (EPA Reg. No. 1258-1249) and Densil DG 45 Fungicide containing 94.5% and 45% B-BIT as the active ingredient, respectively. The objective of the amendment to these labels is to add a two new materials preservation uses. This use site is considered to be a non-food indoor use, therefore dietary exposures were not necessary to assess.

B-BIT is currently registered for preservation of the following types of products: adhesives (non-food contact), caulking compounds, sealants, metal working fluids, polymers, plastics, vinyl, rubber, awnings, tents, and tarpaulins.

4.0. Product Use Profile

Vanquish 100 Antimicrobial is an end-use product that is to be used for preservation of various materials against microbial degradation during the manufacture, storage and service life. The label amendments under review are for the preservation of "Construction Materials" and "Coatings Including Wood Coating and Stains". Vanquish 100 is a liquid containing 94.5% B-BIT used to control bacteria, fungi, and algae in both the wet and dry state of the material. Vanquish 100 is intended to be added to the wet state materials at concentration levels of 0.01% to 0.05% product (or 0.009% to 0.047% ai) or dry state materials at concentration levels of 0.01% to 0.30% product (or 0.009% to 0.047% ai). Specifically for "Construction Materials", Vanquish 100 can be used at level of 0.01% to 0.05% product (or 0.009% to 0.047% ai) for preservation of pulp and paper slurries including emulsions, dispersions, thickeners, pigments, and coatings. Other construction materials such as wood stains and paints/coatings, adhesives, tape joint compounds, spackle, stucco, grout, glazing compounds, wood fillers, sealants, caulks, weather stripping, manufactured paper and paperboard products (i.e., insulation facing, wallboard facing, stationeries and paper packaging), and gypsum, plaster-like materials for ceiling tiles, partitions, dry wall and wallboard are all treated at concentration levels of 0.01% to 0.30% product (or 0.009% to 0.28% ai). For "Coatings Including Wood Coating and Stains", Vanquish 100 can be used at concentration levels of 12 to 120 ppm ai.

Densil DG45 is a liquid containing 45% B-BIT used to control bacteria, fungi, and algae in both the wet and dry state of the material. Densil DG45 has essentially the exact same use directions and application rates (in terms of ai) as Vanquish 100. However, Densil DG45 has a higher application rate for "Coatings Including Wood Coating and Stains" which ranges from 54 ppm to 2701 ppm ai. Furthermore, both labels are intended to be used in materials that do NOT come in contact with food.

Both labels require the use personal protection equipment (PPE) including goggles or face shield and chemical resistant gloves when handling the Vanquish or Densil products. However, since these products are material preservatives, the preserved material (i.e., paint, stains, etc.) will not have a pesticidal label and therefore will not have the PPE requirement when using the material. Thus, professional and residential handlers of paints and stains were assessed without the use of PPE.

5.0. Selection of Toxicological Endpoints for the Non-dietary Assessment

A complete discussion of the endpoints selected for use in the risk assessments can be found in the toxicology memos for D357774 and D357775. A summary of the toxicity endpoints used in this assessment is provided in Table 1.

Table 1. Summary of Toxicological Dose and Endpoints for N-Butyl-1,2- Benzisothiazolin-3-one (Butyl-Bit) for Use in Human Risk Assessment			
EXPOSURE SCENARIO	**DOSE (mg/kg/day)**	**ENDPOINT**	**STUDY**
Acute Dietary	Based on the use pattern, a dietary risk assessment was not required and thus an acute RfD was not needed.		
Chronic Dietary	Based on the use pattern, a dietary risk assessment was not required and thus an acute RfD was not needed.		
Occupational /Residential Exposure			
Short term and Intermediate Incidental (Oral)	NOAEL: 30 MOE = 100*	Ulcerated areas of the stomach	Developmental/Rat [Maternal]
Short-Term, Intermediate-Term, and Long Term (Dermal)	NOAEL: 30 MOE = 100*	Ulcerated areas of the stomach	Developmental/Rat [Maternal] (Assume 100% dermal absorption)
Inhalation (any time period)^	NOAEL: 30 MOE = 100*^	Chemical has a very low vapor pressure, Tox. Category II for acute inhalation, respiratory irritant, (Assume 100% absorption by inhalation)	
Carcinogenicity	No study performed		

NOAEL = no observed adverse effect level.

*10X inter species, 10X intraspecies.

^ Inhalation risk assessment would be needed for potential spry paint approach. It would consider a 90-day inhalation study as a data gap. However if the risk associated with inhalation can pass a MOE of 1,000, the inhalation study data requirement can be waived

6.0. Human Exposure Assessment

Based on the use patterns specified on the revised Vanquish 100 and Densil DG45 labels, RASSB has determined that there is a potential for dermal and inhalation professional and residential exposures to occur. BBIT occupational exposure can occur during the preservation of materials. The "preservation of materials" refers to the scenario of a worker adding the preservative to the material being treated (stain, coating, paint, etc.) through either liquid pour or liquid pump methods. Liquid pour refers to transferring the antimicrobial product from a small container to an open vat. Liquid pump refers to transferring the preservative by connecting/disconnecting a chemical metering pump from a tote or by gravity flow. Furthermore, residential and professional handlers also have the potential for BBIT dermal and inhalation exposure while applying BBIT treated wood stains, paints and coatings. It should be noted that because B-BIT has a low vapor pressure (1.48×10^{-7} mmHg), post-application inhalation exposure to B-

BIT vapors after indoor painting was not necessary to assess. Table 2 presents the B-BIT exposure scenarios necessary to assess.

Table 2. Exposure Scenarios Associated with Occupational and Residential Exposures to B-BIT

Representative Use	Exposure Scenario	Route of Exposure	Application Rate
Materials Preservative			
"Construction Materials"			
Pulp and paper (paper and paperboard products)	Occupational Handler: • Metering pump	ST/IT dermal and inhalation	0.3% ai (0.66% product x 45% ai) (EPA Reg No.1258-1286)
Wood stains, paint and coatings	Occupational Handler: • Open pour • Metering pump Occupational Painter: • Airless sprayer • Brush/Roller	ST/IT dermal and inhalation	0.3% ai (0.66% product x 45% ai) (EPA Reg No.1258-1286)
	Residential Painter: • Airless sprayer • Brush/Roller	ST dermal and inhalation	0.3% ai (0.66% product x 45% ai) (EPA Reg No.1258-1286)
"Coatings Including Wood Coatings and Stains"			
Wood Stain	Occupational Handler: • Open pour • Metering pump Occupational Painter: • Airless sprayer • Brush/Roller	ST/IT dermal and inhalation	0.27% ai (2701 ppm ai) (EPA Reg No.1258-1286)
	Residential Painter: • Airless sprayer • Brush/Roller	ST dermal and inhalation	0.27% ai (2701 ppm ai) (EPA Reg No.1258-1286)
	Occupational Handler: • Open pour • Metering pump Occupational Painter: • Airless sprayer • Brush/Roller	ST/IT dermal and inhalation	0.012% ai (120 ppm ai) (EPA Reg No.1258-1249)
	Residential Painter: • Airless sprayer • Brush/Roller	ST dermal and inhalation	0.012% ai (120 ppm ai) (EPA Reg No.1258-1249)

ST= short-term (1 to 30 days), IT=intermediate-term (1 to 6 months)

6.1 Occupational and Residential Handler Exposures and Risks

The new types of products treated with B-BIT that are on the revised Vanquish 100and Densil DG45 labels are construction materials such as pulp and paper slurries including emulsions, dispersions, thickeners, pigments, and coatings, wood stains and paints/coatings, adhesives, tape joint compounds, spackle, stucco, grout, glazing compounds, wood fillers, sealants, caulks, weather stripping, manufactured paper and paperboard products (i.e., insulation facing, wallboard facing, stationeries and paper packaging), gypsum, and plaster-like materials for ceiling tiles, partitions, dry wall and wallboard. Based on the application rates and the amount of material treated, paperboard products and wood stains were chosen as the representative scenarios for the "Construction materials" while wood stains were chosen as the representative scenario for "Coatings Including Wood Coatings and Stains".

It should be reiterated that although both labels require the use PPE including chemical resistant gloves when handling the Vanquish 100 or Densil DG45 products, the professional and residential painters were assessed without the use of PPE because label restrictions on materials preservative products are not viable mitigation options. Furthermore, because B-BIT has a low vapor pressure (1.48×10^{-7} mmHg), post-application inhalation exposure to B-BIT vapors after indoor painting was not necessary to assess.

The residential and occupational handler scenarios described in Table 2 were assessed to determine dermal and inhalation exposures. No chemical specific residue data were submitted to support this label amendment therefore maximum application rates and default input parameters were used to estimate exposures (or potential daily dose) and risks (or MOEs). The equations presented below were used to determine occupational and residential handlers' exposures and risks.

Potential Daily Dose: Daily dermal or inhalation handler doses are estimated for each applicable handler task by incorporating the maximum application rate, quantity treated/handled in a day, and the applicable dermal or inhalation unit exposure into the following equation:

Daily Exposure: $$PDD = \frac{UE \times AR \times AT}{BW}$$

Where:

PDD	=	Potential daily dose received from exposure to a chemical in a given scenario (mg ai/kg/day)
UE	=	Unit exposure value (mg ai/lb ai) derived from August 1998 PHED data or from 1992 CMA data
AR	=	Maximum application rate based label use instructions (% ai by weight)
AT	=	Amount of material treated/handled (lb/day)
BW	=	Body weight of representative population of interest (70 kg) (USEPA, 1997b).

Margins of Exposure (MOE): Non-cancer dermal and inhalation risks for each applicable handler scenario are determined by using the MOE approach, which is a ratio of the daily dose to the toxicological endpoint of concern. Scenarios where the MOE exceeds the Target MOE are considered to be not of concern.

Margins of Exposure: $MOE = \frac{NOAEL}{PDD}$

Where:

MOE	=	Margin of exposure: value used to represent risk or how close a chemical exposure is to being a concern (unitless);
NOAEL	=	Dose level in a toxicity study, where no observed adverse effects (NOAEL)
PDD	=	Potential daily dose received from exposure to a chemical in a given scenario (mg ai/kg/day).

The assumptions and factors used for the occupational and residential handler scenarios in which surrogate and default data were used include:

Unit Exposure Values: Unit exposure values were taken from the proprietary Chemical Manufacturers Association (CMA) antimicrobial exposure study (USEPA, 1999: DP Barcode D247642), the PHED data presented in HED's PHED Surrogate Guide (USEPA, 1998) or HED's Residential SOPs (USEPA, 1997a and 2001).

- For the ***pulp and paper metering pump*** scenario, the CMA dermal UE of 0.00454 mg/lb ai and inhalation UE of 0.000265 mg/lb ai from the pulp and paper preservative loading study were used. These were based on 7 replicates where the test subjects were wearing a single layer of clothing and chemical resistant gloves.
- For the ***wood stain open pour*** scenarios, the CMA dermal UE of 0.135 mg/lb and inhalation UE of 0.00346 mg/lb ai from the liquid open pour preservative study were used. These are based on only 2 replicates where the test subjects were wearing a single layer of clothing and chemical resistant gloves. Although these exposure scenarios are based on minimal replicates, the exposure values are similar to those found in PHED for similar scenarios.
- For the ***wood stain metering pump*** scenarios, the CMA dermal UE of 0.00629 mg/lb ai and inhalation UE 0.000403 mg/lb ai from the preservative metering pump study were used. These are based on only 2 replicates where the test subjects were wearing a single layer of clothing and chemical resistant gloves. Although these exposure scenarios are based on minimal replicates, the exposure values are similar to those found in PHED for similar scenarios.
- For the ***occupational airless sprayer*** scenario, the PHED UE values for a professional handler applying a pesticide using an airless sprayer were used. The test subjects were staining the outside of a house with an airless sprayer. The dermal unit exposure value (38 mg/lb a.i.) represents a handler wearing long pants, long sleeves and no gloves. The inhalation unit exposure value (0.83 mg/lb a.i.) represents a handler wearing no respiratory protection.

- For the ***occupational brush/roller*** scenarios, the PHED dermal and inhalation UE values for a professional handler applying a pesticide using a paint brush were used. The test subjects were painting a bathroom with a paint brush. The dermal unit exposure value (180 mg/lb a.i.) represents a handler wearing long pants, long sleeves and no gloves. The inhalation unit exposure value (0.28 mg/lb a.i.) represents a handler wearing no respiratory protection.
- For the ***residential airless sprayer*** scenario, the PHED UE values for a residential handler applying a pesticide using an airless sprayer were used. The test subjects were staining the outside of a house with an airless sprayer. The dermal unit exposure value (79 mg/lb a.i.) represents a handler wearing short pants, short sleeves and no gloves. The inhalation unit exposure value (0.83 mg/lb a.i.) represents a handler wearing no respiratory protection.
- For the ***residential brush/roller*** scenarios, the PHED dermal and inhalation UE values for a residential handler applying a pesticide using a paint brush were used. The test subjects were painting a bathroom with a paint brush. The dermal unit exposure value (230 mg/lb a.i.) represents a handler wearing short pants, short sleeves and no gloves. The inhalation unit exposure value (0.28 mg/lb a.i.) represents a handler wearing no respiratory protection.

Quantity treated or handled: The quantities of material treated with the preservative or handled were based on expert input and standard AD assumptions and are presented below.

- For the ***pulp and paper metering pump*** scenario, it was assumed that 500 tons (or 1,000,000 lbs) of pulp and paper can be treated per day.
- For the ***open liquid pour*** and ***metering pump*** scenarios in ***wood stain*** applications, The daily amount of coatings treated that was used in this assessment was based on information provided by experts in the field. The volume of coatings treated can greatly range depending of the manufacturers' size and sophistication. The high-volume manufacturer could produce two 10,000 gallon batches in an 8-hour day where the liquid materials such as the biocide would be automatically pumped into the batch. Therefore, a high-volume manufacturer could produce approximately 20,000 gallons (200,000 lbs = 20,000 gal x 10 lb/gal where 10 lb/gal = paint density) of preserved product (i.e., protective colloids, emulsion resins, water-thinned paints, etc.) in one day. The lower-volume manufacturer could make four 500 gallon batches in an 8-hour day where the liquid materials such as the biocide could be hand metered in or put in via 5 gallon buckets. Therefore, a lower-volume manufacturer could produce approximately 2,000 gallons (20,000 lbs = 2,000 gal x 10 lb/gal where 10 lb/gal = paint density) of product (i.e., paints, coatings, emulsions, etc.) in one day. Based on this information it was assumed that 2,000 gallons of coating was preserved using open loading techniques while 20,000 gallons of coating was preserved using metering pump techniques.
- For the ***occupational airless sprayer*** in the ***wood stain*** scenario, it was assumed that 500 lbs (approximately 50 gallons of stain with a density of 10 lb/gal) of treated paint are used (USEPA 1997a and 2001).